K952660

p.1/2

II 510(k) Summary

SEP 17 1996

B. Braun Medical, Inc
824 Twelfth Avenue
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(610)691-5400

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CONTACT: Mark S. Alsberge, Regulatory Affairs Manager

PRODUCT NAME: Subclavian Catheter

TRADE NAME: Braun Diacath Hemodialysis Catheters

CLASSIFICATION NAME:

Gastroenterology and Urology
Class II, 78 LFJ, Subclavian Catheter
21 CFR 876.5540

SUBSTANTIAL EQUIVALENCE[1] TO:

510(k) number	Name	Applicant
K893439	HEMO-CATH SILICONE DOUBLE LUMEN CATH SL28C & SL40C	MEDICAL COMPONENTS, INC.
K941851	DUAL LUMEN CATHETER (DLC) TRAY	NEOSTAR MEDICAL TECHNOLOGIES, INC.

DEVICE DESCRIPTION:

B. Braun of America Inc. intends to introduce into interstate commerce the Braun Diacath Hemodialysis Catheters in lengths of 170 mm and 250mm. These have the same design and performance characteristics. The intended use is to allow access to the central venous system for blood circulation in pheresis or apheresis processes(i.e. Hemodialysis).

[1] The term "substantially equivalent" as use herein is intended to be a determination of substantial equivalence under the Federal Food, Drug, and Cosmetic Act and relates to the fact that the product can be marketed without premarket approval or reclassification. Such a determination is not intended to be applicable to patent infringement suits or any other patent matter related to

this product or the technology used to manufacture the product.

MATERIAL:

B. Braun Medical certifies that the biocompatibilty tests recommended in the Tripartite Guidance for this category of contact duration will be completed for all the materials used in the manufacture of the device.

SUBSTANTIAL EQUIVALENCE:

The Braun Diacath Hemodialysis Catheters are equivalent in materials, form, and intended use to the catheters currently marketed by Medical Components, Inc. and Neostar Medical Technologies, Inc. There are no new issues of safety or effectiveness raised by the Braun Diacath Hemodialysis Catheters.

SAFETY AND EFFECTIVENESS:

All finished products are tested and must meet all required release specifications before distribution. The array of testing required for release include, but are not limited to; sterility, pyrogenicity (endotoxin/ LAL Method), physical testing, visual examination (in process and finished product).

The physical testing is defined by Quality Control Test Procedure documents. These tests are established testing procedures and parameters which conform to the product design specifications.

The testing instruction records for each of the individually required procedures are approved, released, distributed and revised in accordance with document control GMP"s.